Workshop on Statistics and Innovation for Industry 4.0

Statistics for Continuous Improvement of Manufacturing Process of Ultrasound Probes for Medical Imaging

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Milestones

A history of people and technology

1982

Esaote born inside Ansaldo (IRI Finmeccanica Group), a state-owned company,

1983-1988

Ansaldo internal division becomes part of EsaControl, merging with Ote Biomedica. Creation of Esaote Biomedica

1992

Internationalisation process starts. First acquisition in the USA (Biosound).

1994

Esaote becomes a private company through an innovative Management Buy-Out

1996-2003

Esaote quoted at Milan Stock Exchange

2006

2nd Management Buy-out with leading financial groups and 99 Esaote managers and directors

2009

3rd MBO with new investors

2018

Change of Esaote's ownership: Esaote is acquired by a Consortium of leading Chinese investors

What we do

A long-term engagement

- ULTRASOUND DIAGNOSTIC IMAGING
- DEDICATED MRI
- HEALTHCARE IT
- GLOBAL SERVICE

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Esaote Ultrasound (US) systems

Speed innovation

Platform strategy

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Esaote in the world

R&D

3 R&D Centres
Genoa, Florence, Maastricht

3 Production Sites
Genoa, Florence, Maastricht

1121 employees

14 Branches
Belgium, The Netherlands, France, Germany, Spain, United Kingdom, Russia, China, Hong Kong, India, Argentina, Mexico, United States

80 Local Distributors

Esaote facilities

HEADQUARTERS
ULTRASOUND R&D Centre
MEDICAL IT –
GENOA ERZELLI, Italy

Esaote facilities

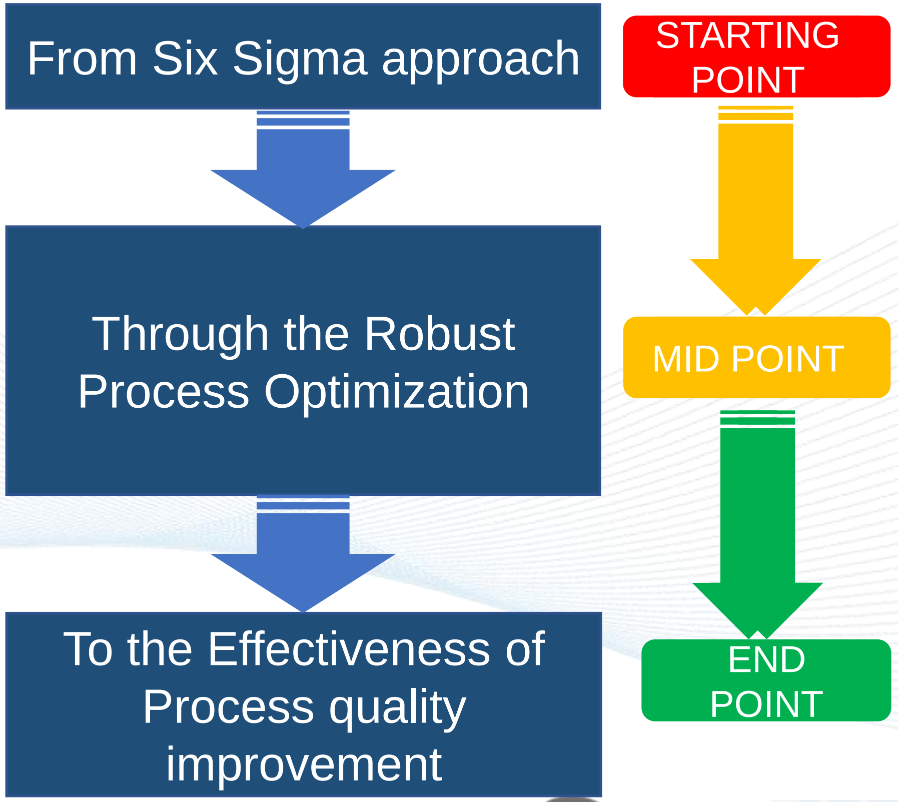
CENTRE OF EXCELLENCE FOR PROBES PRODUCTION – FLORENCE, Italy

Esaote facilities

INTERNATIONAL HUB – SESTO FIORENTINO, FLORENCE, Italy

Outline

- Scenario;
- Purpose of the study;
- PDCA (Plan-Do-Check-Act) methodology implementation;
- Analysis conducted via advanced statistical methods (i.e. statistical modelling);
- Scanning Acoustic Microscopy (SAM) for latent failure detection;
- Results;
- Conclusions.



Scenario

1 Ultrasound scanner

2 Keyboard and touch panel

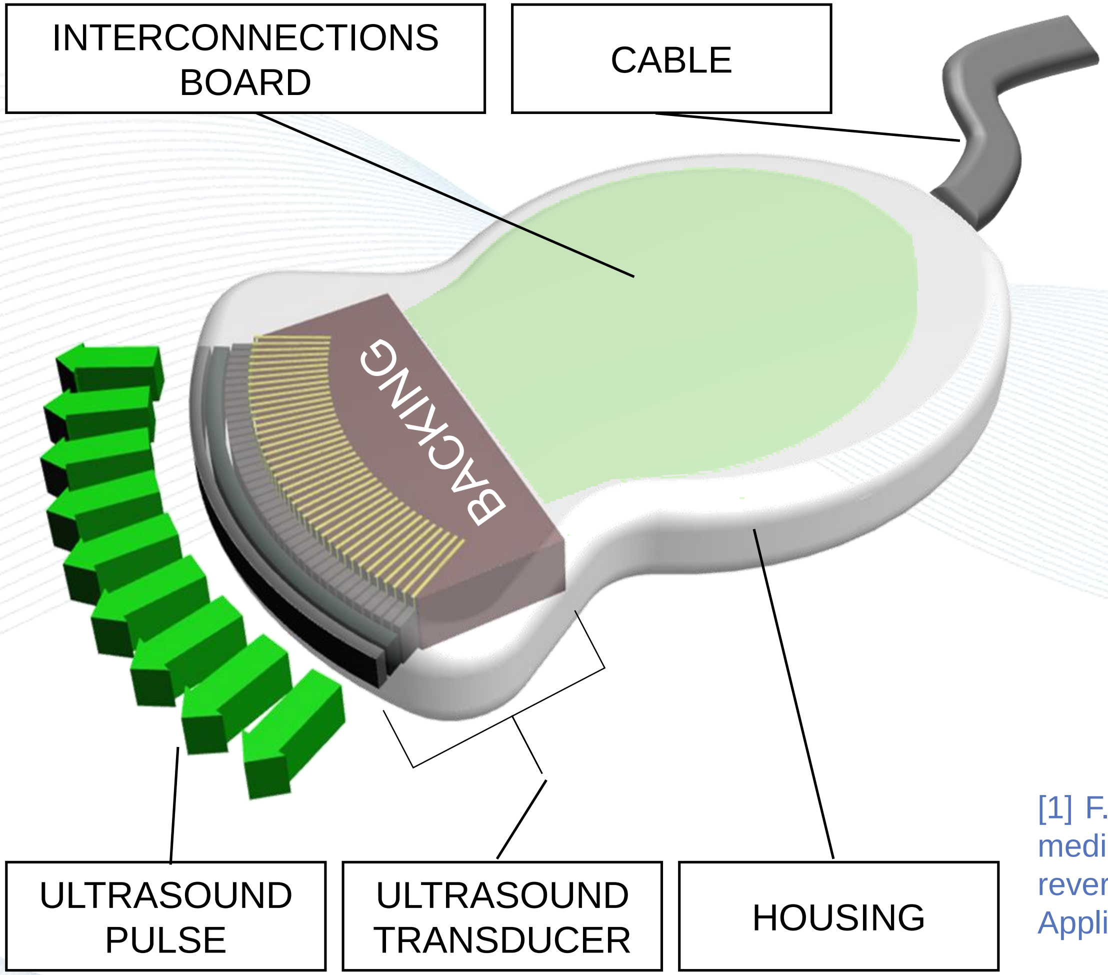
3 Monitor

4 Ultrasound probes

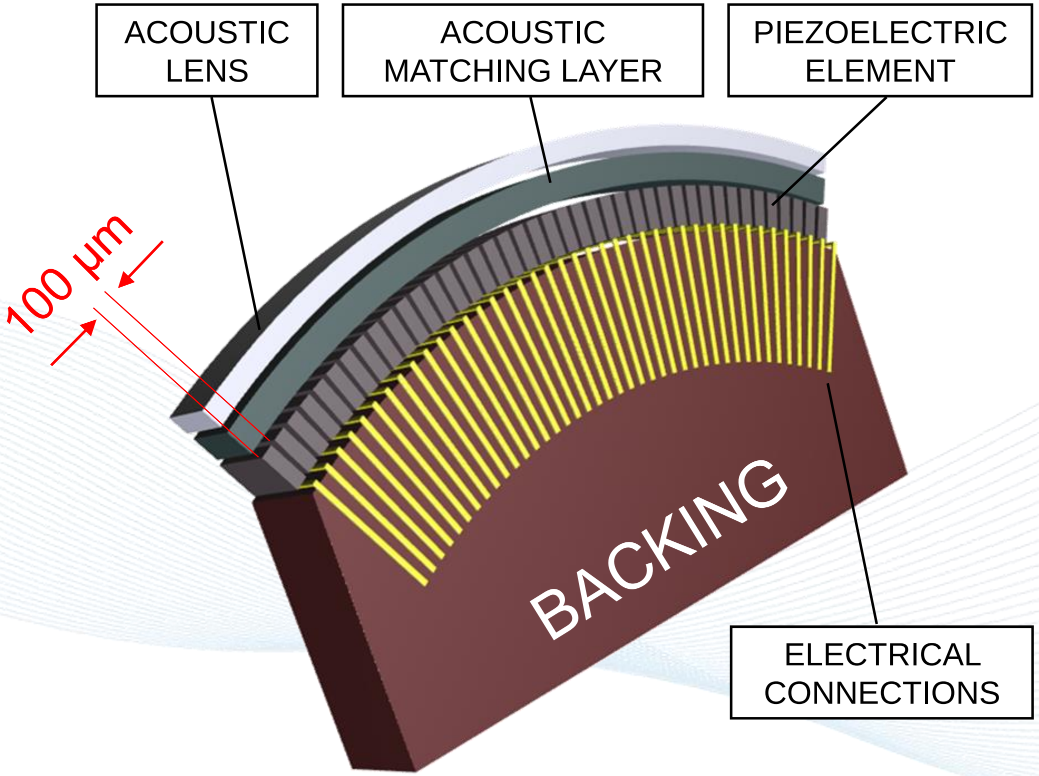
The **probe** is the element in direct contact with the patient and it is used to generate and to receive ultrasound waves.

Ultrasound probe and transducer: main components[1]

PROBE



TRANSDUCER



[1] F. Bertocci, L. Francalanci, R. De Luca, M. Bassani, F. Gelli, P. Palchetti, «Design of medical ultrasound probe: Measurement system for the characterization of reverberations», IEEE International Symposium on Medical Measurements and Applications (MeMeA), pp. 1-6, *2018*.

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Purpose: continuous improvement of the manufacturing process

- Assign and Mitigate the **RISK LEVEL** for each complex manufacturing stage

- Make **EFFICIENT** and improve the manufacturing process in Industry 4.0 scenario

STAGE #1
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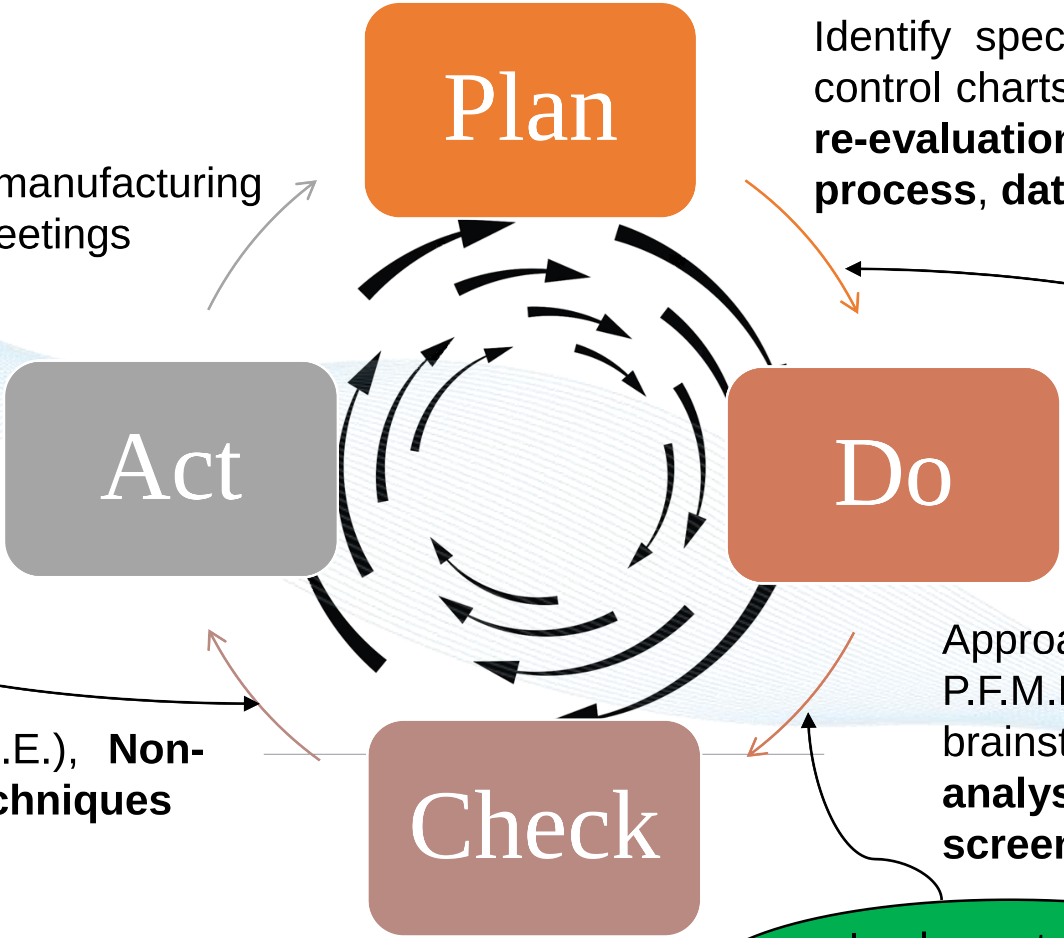
STAGE #23

MANUFACTURING PROCESS

P.D.C.A. (Plan-Do-Check-Act) cycle method for continuous improvement of manufacturing process

Identify special causes of failure, control charts, root cause analysis, **re-evaluation of manufacturing process**, **data collection**

F.M.E.C.A., **control charts**, manufacturing control plans, brainstorming meetings



Identification of MAIN FAILURE MODES and RISKS

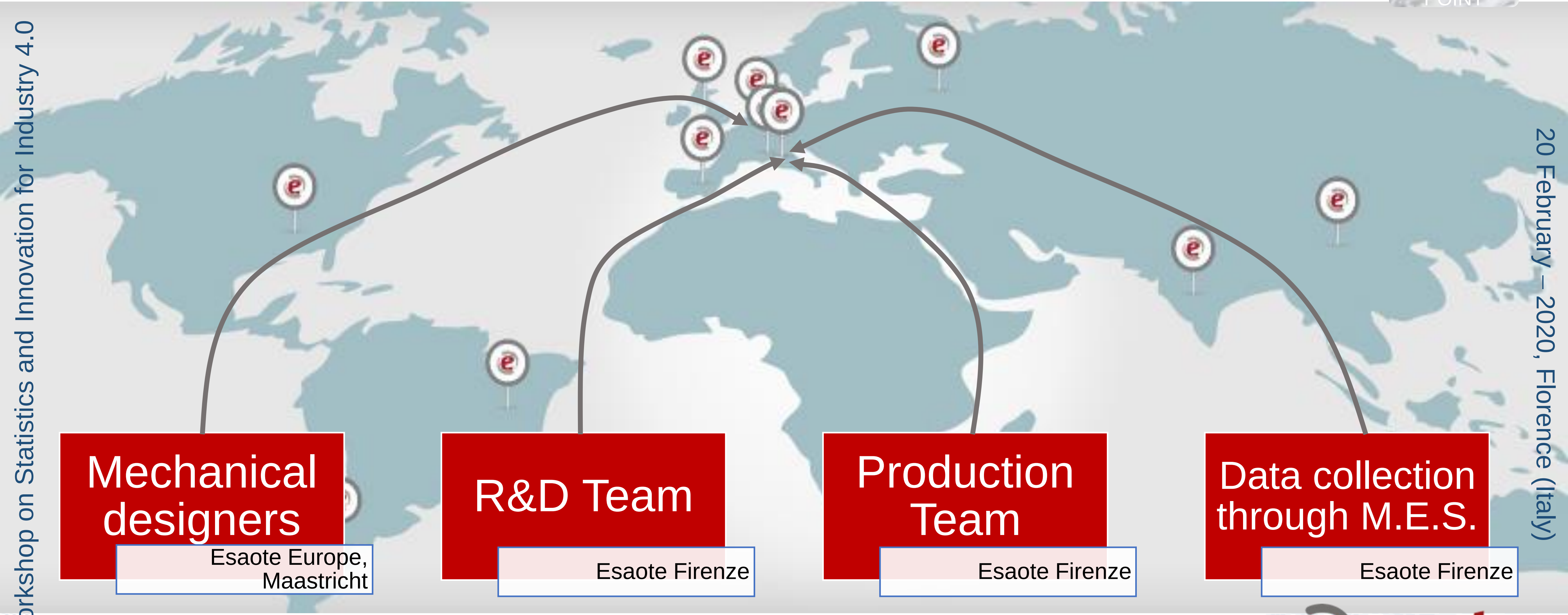
Detection of LATENT FAILURES/DEFECTS

Approach by using S.I.P.O.C., F.T.A., P.F.M.E.A., R.P.N., C.O.P.Q. estimation, brainstorming meetings, **dataset analysis, factors and responses screening**

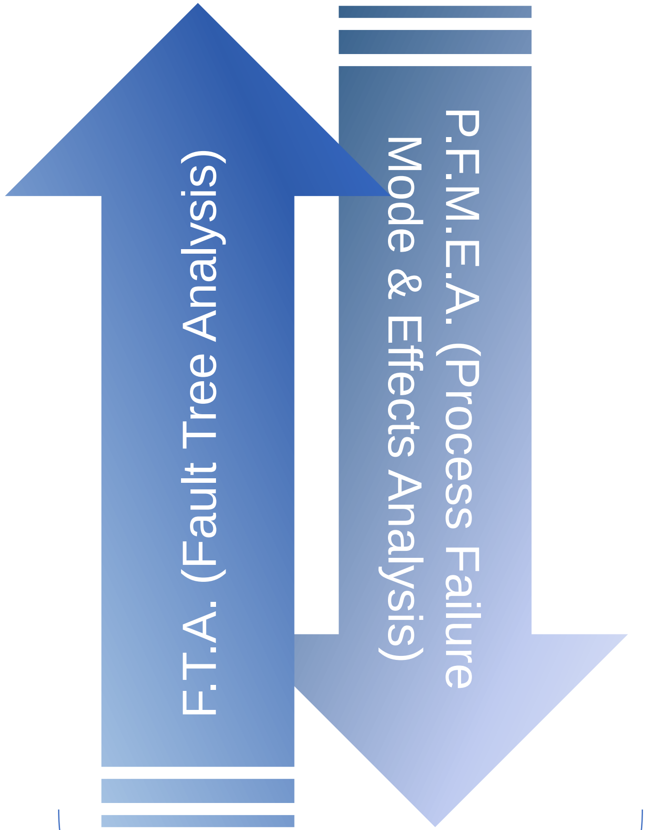
Design of Experiments (D.o.E.), **Non-destructive testing (NDT) techniques**

Implementation of REGRESSION MODELS

The TEAM devoted to the continuous improvement



Risk and failure analysis on the manufacturing process



Well-known methods for root cause analysis and for potential failure modes

Risk level

- Low
- Medium
- High
- Very high

- Measurement

STARTING POINT

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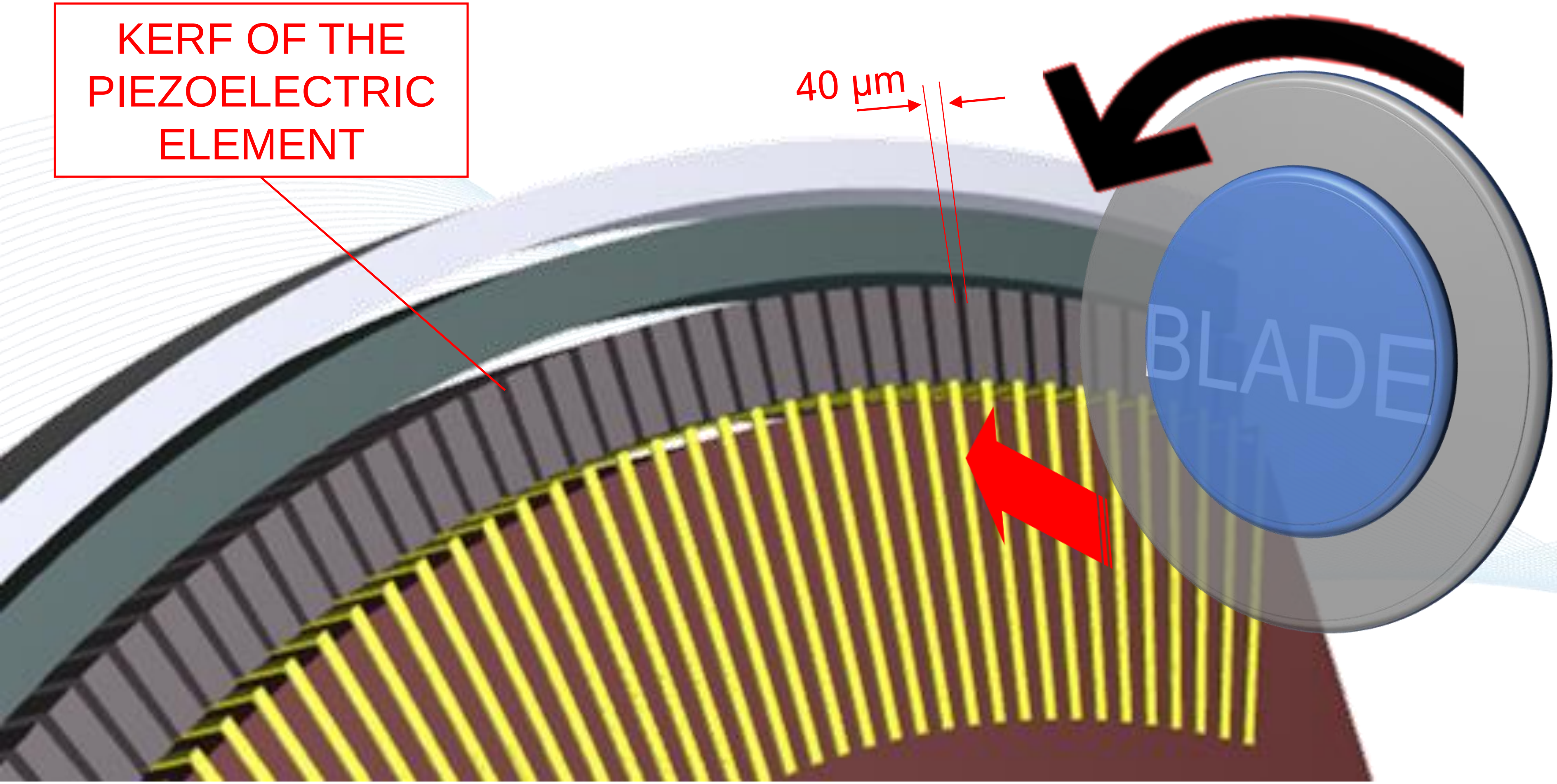
STARTING POINT → MID POINT → END POINT

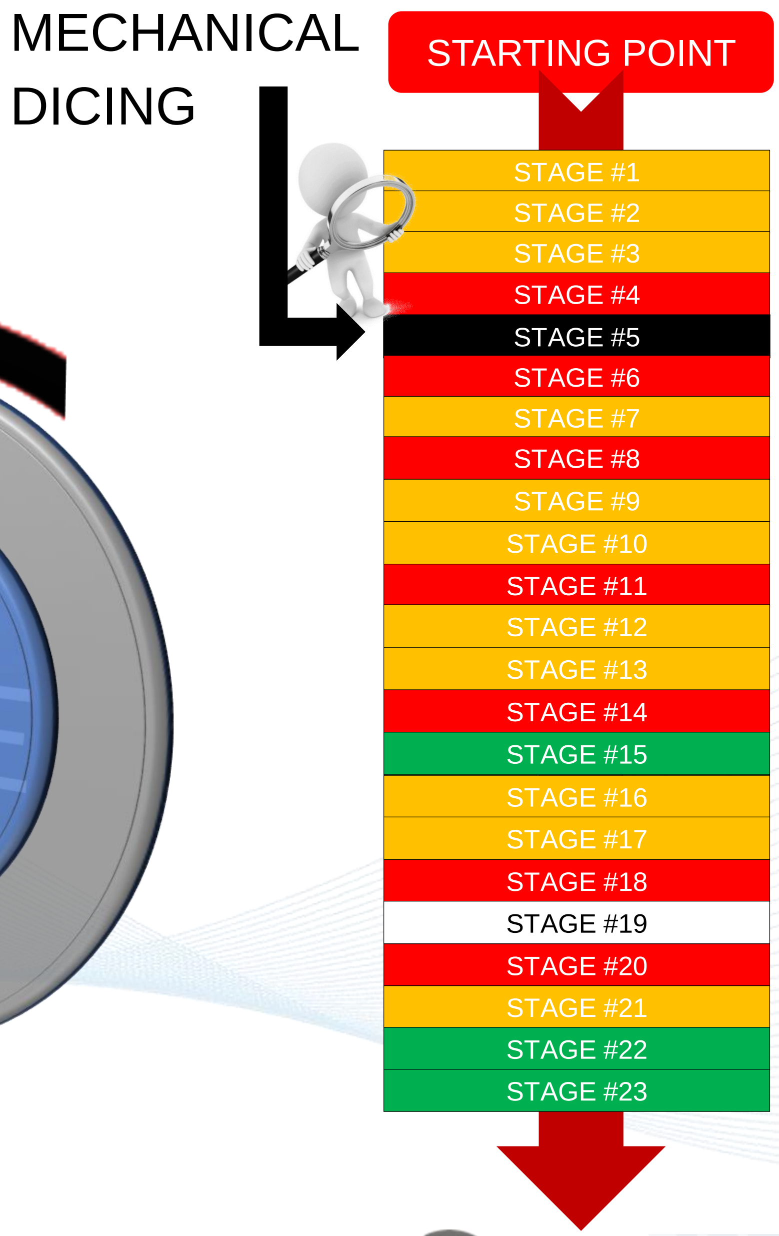
ONLY OPTICAL INSPECTION

STAGE #5

MECHANICAL DICING

Mechanical dicing[2]





[2] F. Bertocci, A. Grandoni, «Corrosion of Tin-Indium Solder during the Manufacturing Process of Biomedical Ultrasound Transducer», 22° European Microelectronics and Packaging Conference & Exhibition (EMPC), pp. 1-8, *2019*.

Implementation of a dataset for the statistical modelling

STARTING POINT
MID POINT
END POINT

- The **strenuous collection** of historical (observational) data has been carried out by means of:
  - Processing cards;
  - Control charts;
  - **M.E.S. (Manufacturing Execution System)**.

- Database implementation:
  - Electronic spreadsheet.

- Data analysis for the statistical modelling:
  - Dedicated software, i.e. **S.A.S.** (Statistical Analysis System);
  - **Strong collaboration between the engineering and the statistics**.

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Key points of the collaboration between engineers and statisticians[3]

- **Re-examination** of each manufacturing stage under critical point of view;
- Need to add electrical and mechanical **in-process** measurements (more factors, more responses);
- Identification and analysis of **factors** that can influence the variability of the process **never evaluated by the engineering**;
- Manage and organize the analysis by considering more than **36 different factors and 38 response variables** (qualitative and quantitative);
- Distinction between **systematic, noise and block effects** for defining and planning the Design of Experiments.

[3] R. Berni, F. Bertocci, N.D. Nikiforova, G.G. Vining, «A Tutorial on Randomizing versus Not Randomizing Split-Plot Experiments», Quality Engineering, *Vol. 32*, n°1, pp. 25–45, *2020*.

Statistical models for improving the manufacturing process

STARTING POINT
MID POINT
END POINT

- **Multiple linear regression model for the variation of the response (i.e. sensitivity of the US probe):**

$Y_{\text{RESPONSE VARIATION}} = \beta_0 + \beta_1 \cdot X_{\text{WORKER @STAGE 4}} + \beta_2 \cdot X_{\text{WORKER @STAGE 8}} + \beta_3 \cdot X_{\text{WORKER @STAGE 11}} + \beta_4 \cdot X_{\text{DICING MACHINE @STAGE 5}} + \beta_5 \cdot X_{\text{N° OF BLADE RE-USE @STAGE 5}} + \beta_6 \cdot X_{\text{DAYS BETWEEN STAGE 2 AND STAGE 4}} + \beta_7 \cdot X_{\text{DAYS BETWEEN STAGE 6 AND STAGE 8}} + \beta_8 \cdot X_{\text{DAYS BETWEEN STAGE 8 AND STAGE 11}} + \beta_9 \cdot X_{\text{DAYS BETWEEN STAGE 11 AND STAGE 14}} + \beta_{10} \cdot X_{\text{WORKPIECE HEIGHT @STAGE 6}}$

- **Logistic Regression model for the compliance of the US probe:**

$Y_{\text{PASS/NO PASS}} = \beta_{00} + \beta_{11} \cdot X_{\text{N° OF BLADE RE-USE @STAGE 5}} + \beta_{22} \cdot X_{\text{DICING MACHINE @STAGE 5}} + \beta_{33} \cdot X_{\text{WORKING @STAGE 8}} + \beta_{44} \cdot X_{\text{WORKER @STAGE 11}} + \beta_{55} \cdot X_{\text{TIMING OF BONDING PROCESS @STAGE 2}} + \beta_{66} \cdot X_{\text{DAYS BETWEEN STAGE 2 AND STAGE 6}} + \beta_{77} \cdot X_{\text{DAYS BETWEEN STAGE 8 AND STAGE 14}}$

Main results after Statistical modelling (1/2)

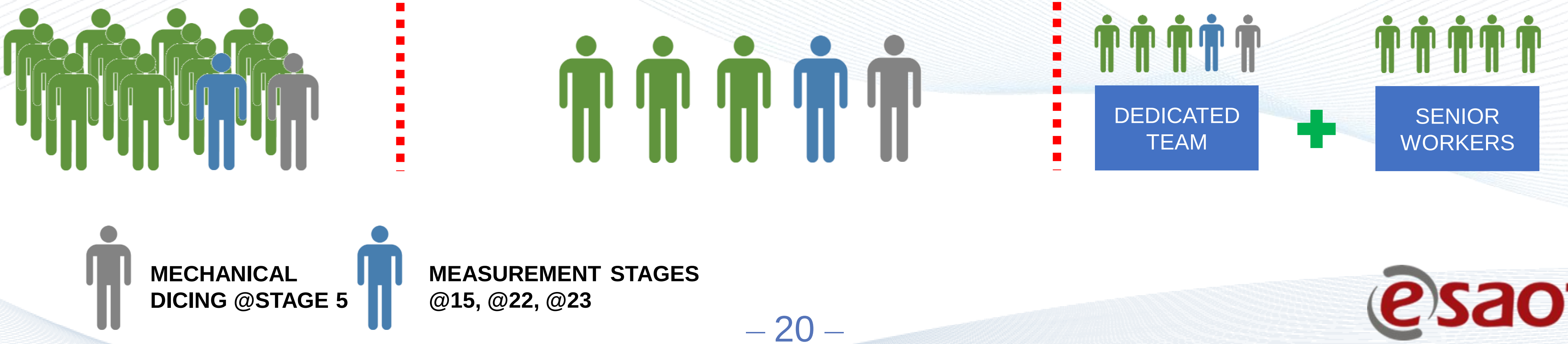
❖ The **workers** play a key role in the variability of the production process

REDUCING THE VARIABILITY OF THE PRODUCTION

16 operators initially involved in the production process.

DEDICATED TEAM OF WORKERS: less variability of the production process as a contribution to reducing the probability of failure.

Probe production increase request: choice of an extended DEDICATED team.



Main results after Statistical modelling (2/2)

STARTING POINT		MID POINT
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STAGE #5		STAGE #5
STAGE #6	Engineering & Statistics for the continuous improvement of the manufacturing process	STAGE #6
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STAGE #23		STAGE #23

- Need to implement a D.o.E. (Design of Experiments) devoted to the first stages of the process for the factors screening;
- The interaction between factors are significant and/or considerable;

Risk level

- Low
- Medium
- High
- Very high

- Measurement

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Non-Destructive Testing (NDT) for multilayered structures with thickness of some microns

MID POINT

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Risk level

- Low
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STAGE #5

MECHANICAL DICING

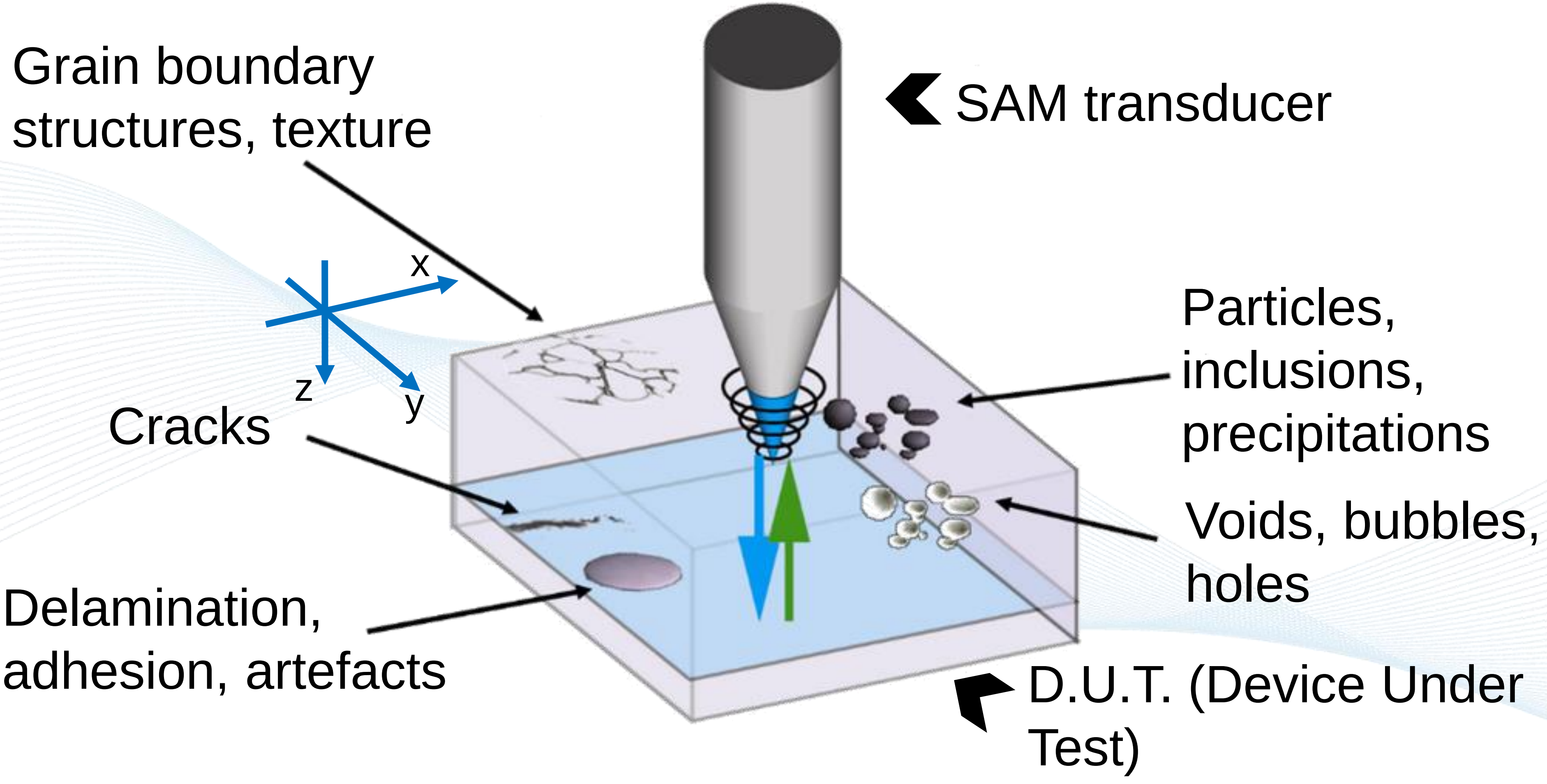
Infrared thermography: influenced by ambient factors (i.e. moisture, temperature)

Optical microscopy: strongly limited to a surface investigation

X-ray computed tomography (XCT): low resolution and no-effective in case of layers with high content of lead, Pb (case of piezoelectric element)

Scanning Acoustic Microscopy (SAM): very promising for the inspection of defects and delamination occurring during the manufacturing process

Scanning Acoustic Microscopy (SAM) [1] for In-process quality monitoring[4]



[4] F. Bertocci, A. Grandoni, T. Djuric-Rissner, «Scanning Acoustic Microscopy (SAM): A Robust Method for Defect Detection during the Manufacturing Process of Ultrasound Probes for Medical Imaging», Sensors MDPI, *Vol. 19*, pp. 4868–4887, *2019*.

Scanning Acoustic Microscopy (S.A.M.) analysis

STARTING POINT
MID POINT
END POINT

MID POINT

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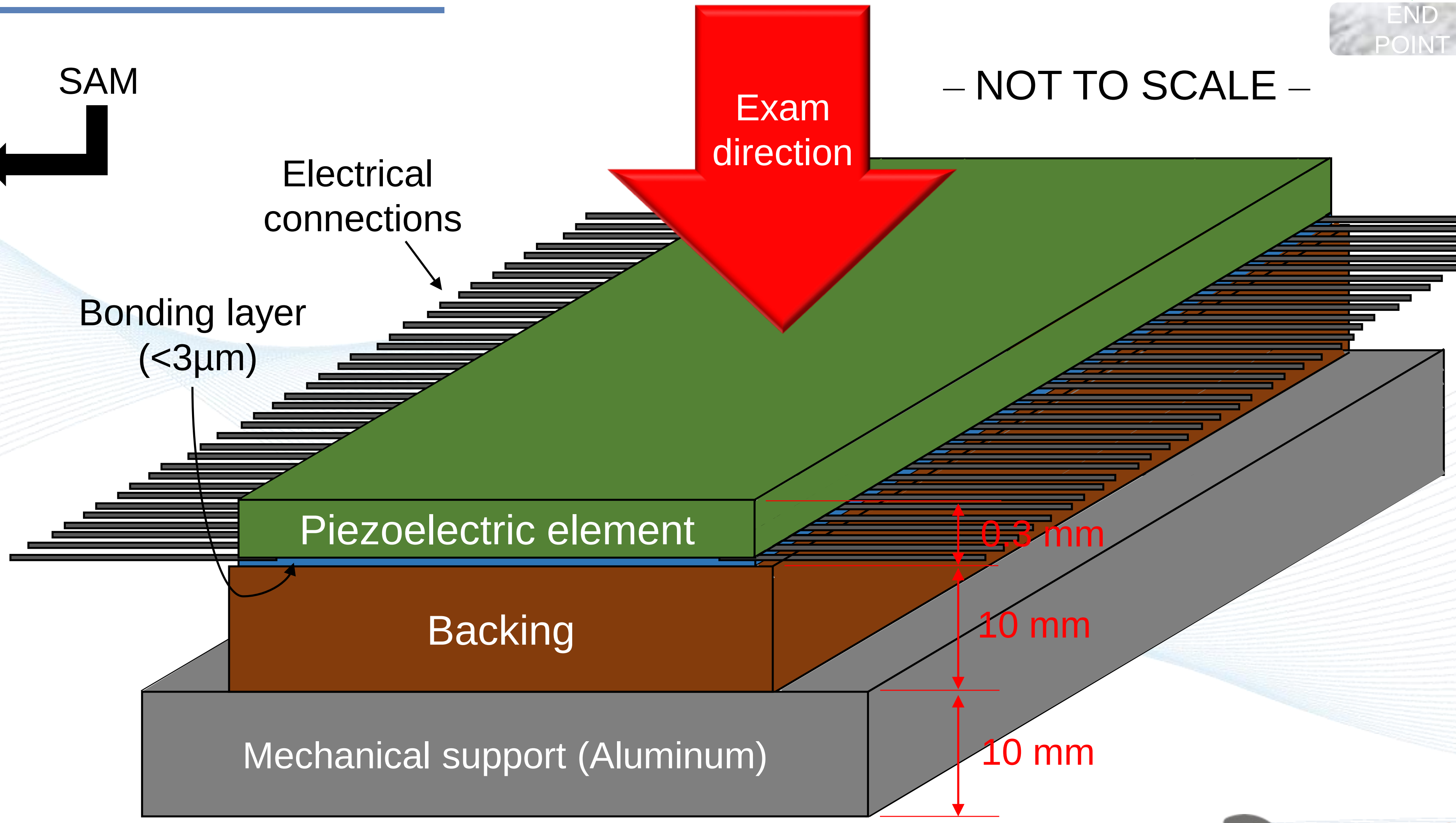
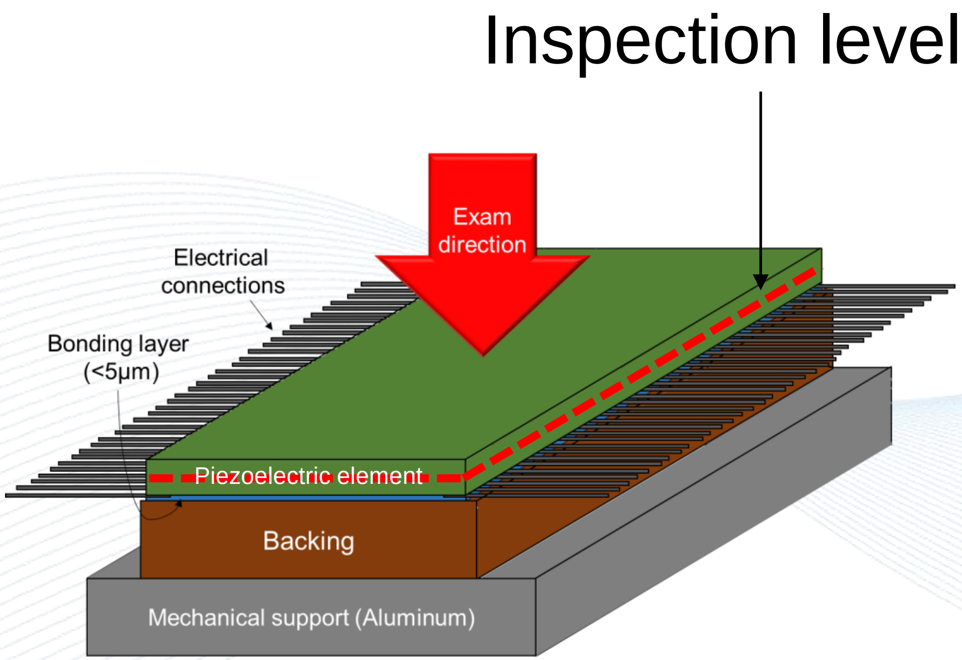
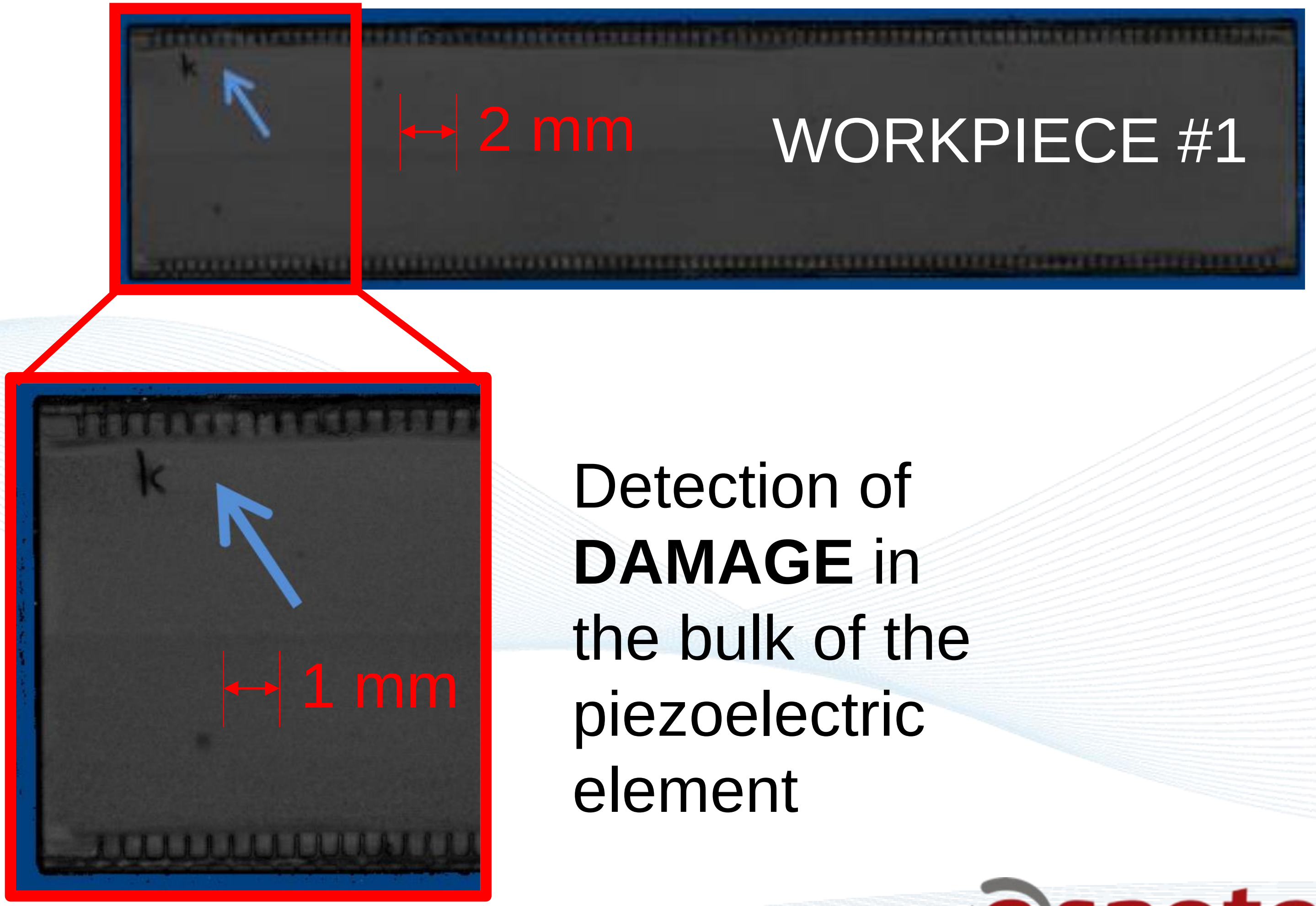
SAM

– NOT TO SCALE –



Preliminary results of SAM investigation





Detection of **DAMAGE** in the bulk of the piezoelectric element

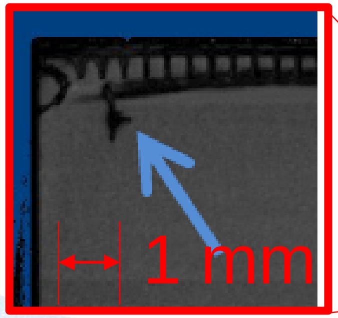
STARTING POINT

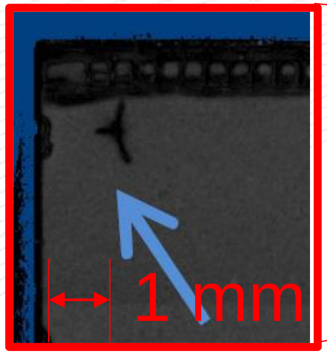
MID POINT

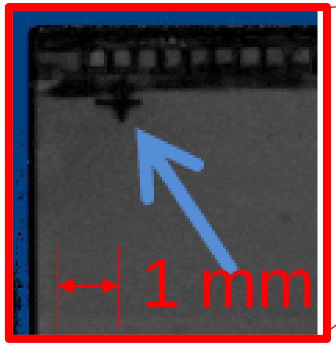
END POINT

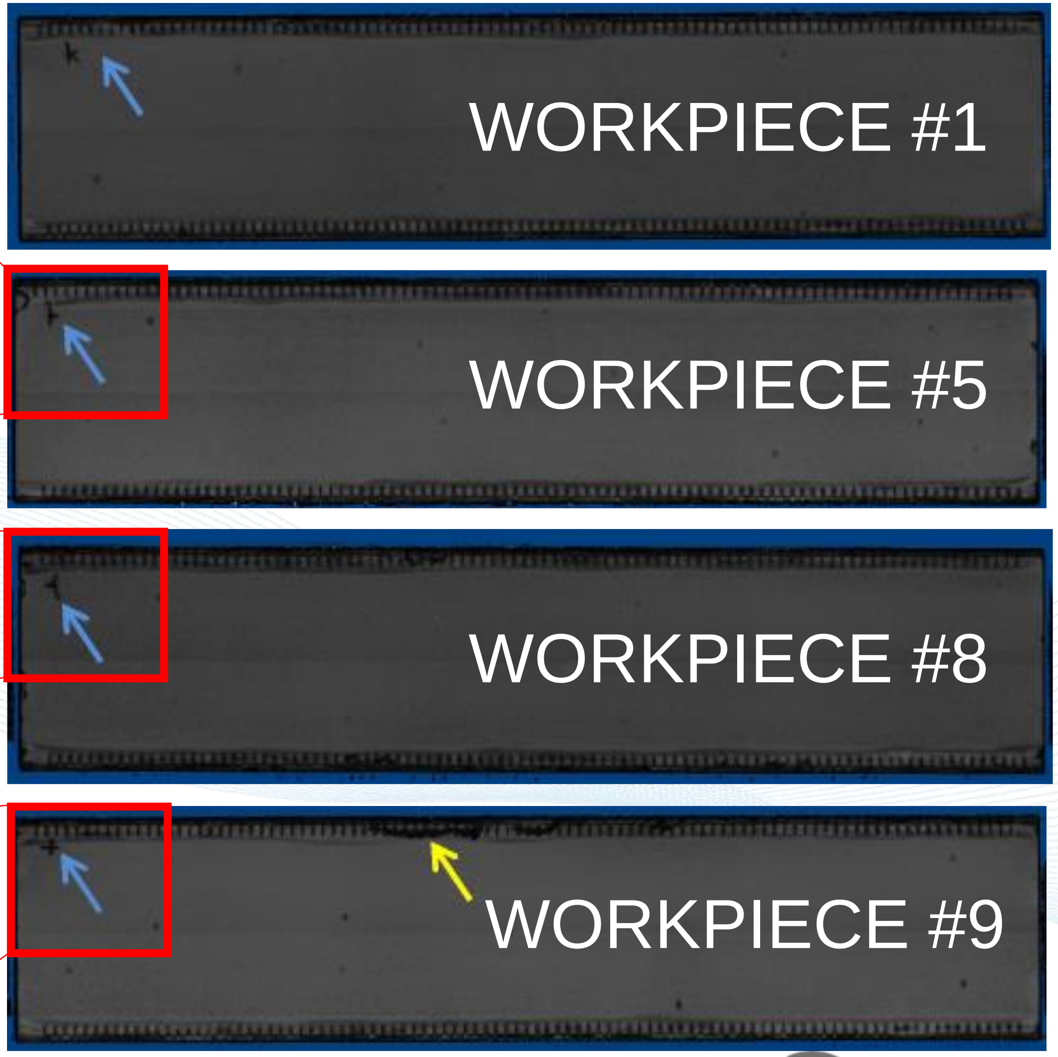
Results of SAM measurement campaign

The DAMAGE is a crack (**latent failure**) in the same location of different workpieces

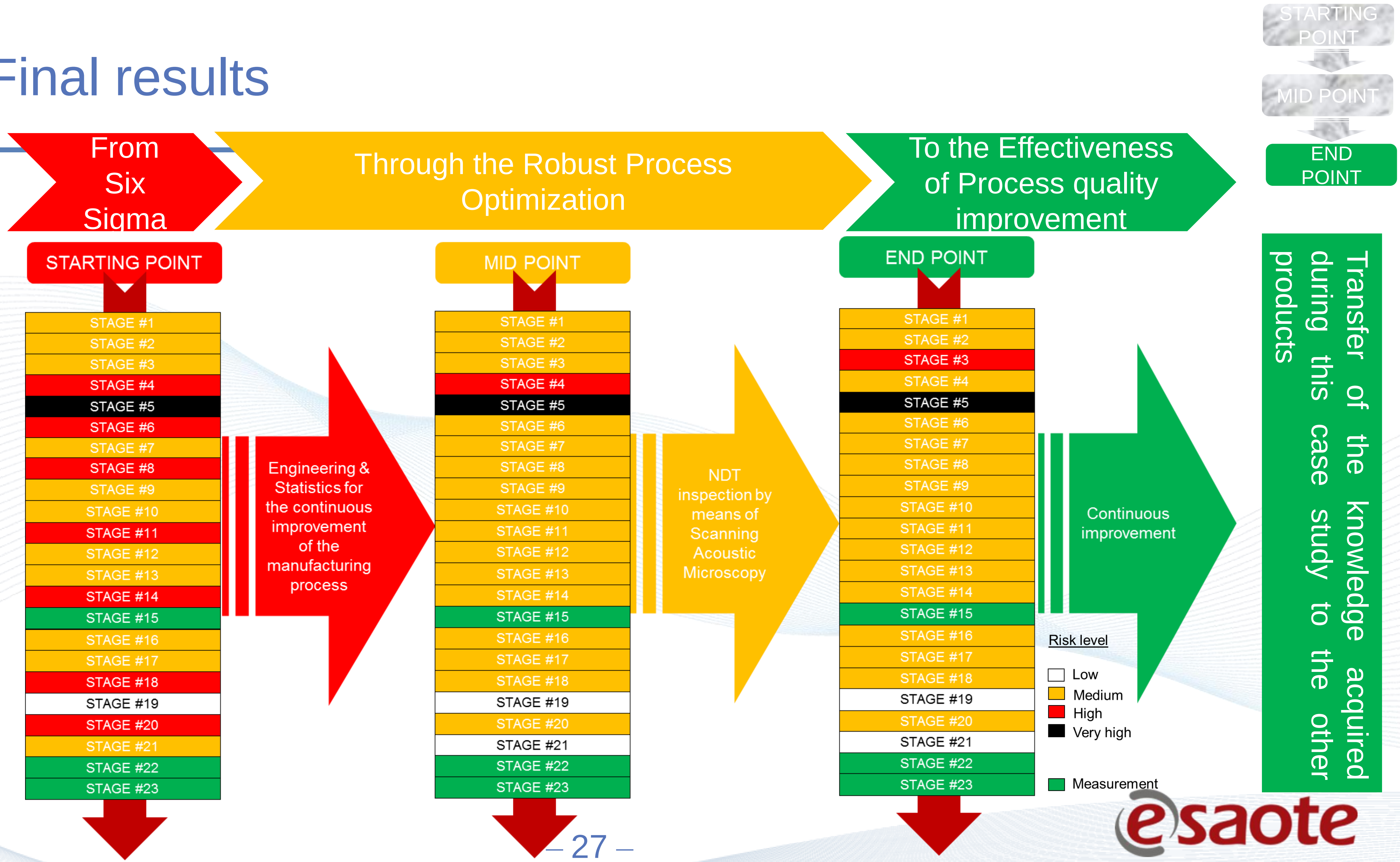








Final results



Conclusions

- The application of advanced method for robust process optimization made **efficient** and **effective** the improvement of US probes manufacturing process;
- The **multidisciplinary research** based on statistics has been a source of improvement opportunities and decisive in the **Industry 4.0 scenario**;
- The presented approach driven by **statistical modelling** allows the engineering to distinguish the **weak points** of the process and to **provide the corrective actions**;
- **SAM** is a robust NDT technique that provides an efficient solution for quick identification and location of defects in multi-layered structures;
- The **human factor** was decisive for reducing the variability of the production process and for increasing the quality of the product.

Thanks for your attention

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its products is available at
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